

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

JO HUSKEY, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-05201

ETHICON, INC., et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER
(Motions in Limine and Remaining Daubert Motion)**

Pending before the court are the Plaintiffs' Motions in Limine [Docket 280], the Defendants' Omnibus Motion in Limine [Docket 282], the Defendants' Motion to Limit the Testimony of Erin Teeter Carey, MD MSCR [Docket 275], and the Defendants' Motion in Limine to Exclude Evidence of Plaintiffs' Allegations of Spoliation [Docket 274]. In accordance with this opinion, the Plaintiffs' Motions in Limine [Docket 280] are **DENIED**, the Defendants' Omnibus Motion in Limine [Docket 282] is **DENIED in part** and **GRANTED in part**, the Defendants' Motion to Limit the Testimony of Erin Teeter Carey, MD MSCR [Docket 275] is **GRANTED**, and the Defendants' Motion in Limine to Exclude Evidence of Plaintiffs' Allegations of Spoliation [Docket 274] is **GRANTED**.

I. Background

This case is one of more than 60,000 that have been assigned to me by the Judicial Panel on Multidistrict Litigation in seven MDLs involving pelvic mesh products. Approximately 20,000 of these cases reside in the *In re Ethicon, Inc.* MDL, MDL No. 2327. The device at issue in this case

is the Gynecare TVT Obturator (“TVT-O”), manufactured by the defendants, Ethicon, Inc. and Johnson & Johnson, Inc. (collectively, “Ethicon”). The TVT-O is a medical device that includes a mechanism used to place a mesh tape, or sling, under the urethra to provide support to the urethra to treat stress urinary incontinence. After resolving the parties’ motions for summary judgment, the following claims remain for trial: negligence, strict liability for design defect, strict liability for failure to warn, negligent infliction of emotional distress, gross negligence, and punitive damages. (*See* Short Form Compl. [Docket 1], at 4-5; *see generally* Mem. Op. & Order [Docket 272]).

II. Motions in Limine

The plaintiffs filed 15 motions in limine and Ethicon filed 19. Many of these motions are silly. For the vast majority of them, I simply cannot make a substantive ruling at this time without knowing the particular piece of evidence that a party seeks to introduce or argument that a party seeks to make. Nor can I make a ruling without knowing the context in which that party seeks to introduce such evidence or argument. In short, a blanket exclusion of such evidence or argument is premature at this time. For instance, Ethicon asks that I exclude “all evidence and argument” related to “off-color” emails that are irrelevant, unfairly prejudicial, and inadmissible hearsay. (Ethicon’s Mem. in Supp. of Omnibus Mot. in Limine [Docket 283], at 30). Ethicon points to a few emails, but asks me to rule on many that I have not seen. It is probable that some of the emails are inadmissible, but I need not make a ruling at this stage. Similarly, the plaintiffs seek to exclude all evidence “related to” Ms. Huskey’s divorce, including a 2001 court file containing documents related to the divorce. (Mem. in Supp. of Pls.’ Mots. in Limine [Docket 281], at 3). Again, while much of this evidence is likely inadmissible, I cannot rule at this stage on the admissibility of an entire file produced in discovery. Where evidence is not admissible pursuant to the Federal Rules of Evidence, it will not be admitted. Otherwise, it will be admitted. The parties

are represented by able counsel, and I trust they can distinguish the difference. I expect counsel to know the rules of evidence and to offer only matters which they believe in good faith to be admissible. I expect objections only where the opposing party believes in good faith that the evidence is inadmissible. I expect lawyers to make informed decisions about the proof of their case without asking me elementary questions.

Many of the pending motions in limine are unopposed. There is no need for me to rule on such motions. The parties are expected to abide by these concessions.

For these reasons, the following motions are **DENIED without prejudice**: Ethicon's Motions in Limine Nos. 1, 3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 16, 17, 18, 19; and the plaintiffs' Motions in Limine Nos. 2, 3, 4, 5, 6, 7, 8, 9, 13, 14, 15. My denial of these motions without prejudice is not an invitation for the parties to relitigate these matters at trial. The parties are cautioned to use their best judgment in offering and objecting to evidence.

Having denied the majority of the motions in limine without prejudice, several remaining motions in limine nevertheless merit rulings at this time. I discuss those motions below.

- **Plaintiffs' Motion 10: To Exclude Reference to TVT-O Being the "Gold Standard"**

The plaintiffs argue that Ethicon should be prohibited from presenting evidence or argument that the TVT-O is the "gold standard" for the treatment of SUI. The plaintiffs believe that this term should be excluded as irrelevant, overly prejudicial, and misleading because it is imprecise and different experts disagree about what exactly it means. I have already addressed this issue with regard to Ethicon's other product, the TVT. *See In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-cv-4301, 2014 WL 505234, at *3 (S.D. W. Va. Feb. 5, 2014). Whether the TVT-O is regarded as the "gold standard" is highly probative: it goes to the very essence of whether the TVT-O is unreasonably dangerous and whether there existed safer

alternative designs. *See Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 347 (Ill. 2008) (“[T]he existence of a feasible alternative design and the balancing of risks and benefits are relevant considerations in a strict product liability design defect case[.]”). If the plaintiffs believe that “gold standard” is imprecise, inaccurate, or confusing, they may vigorously cross-examine witnesses. Accordingly, this motion in limine is **DENIED**.

- Plaintiffs’ Motion 11: To Exclude Evidence of AUGS-SUFU Position Statement

The plaintiffs seek to exclude a position statement authored by the American Urogynecological Society and the Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction. The position statement endorses polypropylene mesh midurethral slings as the “worldwide standard of care for the surgical treatment of stress urinary incontinence.” (Position Statement [Docket 280-20], at 1). The plaintiffs argue that the Position Statement lacks probative value because it was authored by individuals associated with mesh manufacturers to combat plaintiffs’ lawyers and to assist Ethicon in litigation. (*See* Mem. in Supp. of Pls.’ Mots. in Limine [Docket 281], at 20-22). That may or may not be true. The plaintiffs are free to fully explore the issue during cross-examination.

This evidence is likely admissible for several reasons. First, to the extent that the Position Statement is relied upon by an expert witness, it may be admissible under the learned treatise exception to the hearsay rule. *See* Fed. R. Evid. 803(18). Second, under Rule 703, experts are permitted to rely on otherwise inadmissible information provided that they “would reasonably rely on those kinds of facts or data in forming an opinion on the subject.” Fed. R. Evid. 703. Third, Ethicon’s state of mind is relevant to the punitive damages claim, and “[a]n out-of-court statement that is offered to show its effect on the hearer’s state of mind is not hearsay under Rule 801(c).” *United States v. Thompson*, 279 F.3d 1043, 1047 (D.C. Cir. 2002). Provided that Ethicon properly

introduces this evidence, the plaintiffs' motion on this issue is **DENIED**.

- **Plaintiffs' Motion 12: To Exclude Evidence Regarding the Preservation of Jo Huskey's Explanted Mesh**

After Ms. Huskey's mesh was explanted, it was discarded by her hospital according to its normal retention policies. (Defs.' Resp. to Pls.' Mots. in Limine [Docket 300], at 15-16). Accordingly, neither party had an opportunity to analyze the explanted mesh. The plaintiffs move to exclude any reference to the fact that the mesh was not preserved. The plaintiffs argue that Illinois law does not require them to produce the explanted TVT-O in order to prove their case. *See DiCosolo v. Janssen Pharm., Inc.*, 951 N.E.2d 1238, 1244 (Ill. Ct. App. 2011) ("[T]he unavailability of the product does not preclude a plaintiff from proving that a product was defective through circumstantial evidence."). While that is true, it does not mean such evidence is irrelevant. Whether Ms. Huskey's mesh explant is available may be relevant to the credibility of the plaintiffs' expert witnesses, among other things.

The plaintiffs also contend that any suggestion that the mesh was not preserved will improperly imply that the mesh was lost as a result of attorney misconduct. I agree that this is a risk, and therefore Ethicon will not be permitted to argue or suggest that plaintiffs' counsel acted inappropriately by failing to preserve the explant. Accordingly, this motion is **DENIED**.

- **Ethicon's Motion 2: To Exclude Brian Luscombe's Internal Marketing Presentation**

Ethicon moves to exclude an internal marketing presentation mimicking David Letterman's "Top Ten" lists. The presentation is styled as the "Top Ten Reasons to Pursue Gynecare TVT Obturator Approach." (Presentation [Docket 282-2]). It then lists ten sarcastic reasons that surgeons should use the TVT-O, including:

10: For the surgeon who likes to point their needles too far lateral (and hit things like the external iliac), this gives them something new to go after!!!!

9: Since the needles don't enter the retropubic space, bladder perforations SHOULD be reduced

...

7: Small Bowel . . . when things just aren't in the right place . . . enough said

...

1: MAMA NEEDS A NEW PAIR OF SHOES!!!!

(*Id.*). Ethicon contends that the presentation was intended as a “sarcastic, lighthearted ‘ice breaker’ for Ethicon’s sales force, rather than a serious presentation.” (Ethicon’s Mem. in Supp. of Omnibus Mot. in Limine [Docket 283], at 3). According to Ethicon, the employee who created it designed it as a joke to lighten up training events for sales representatives. (*See id.*). Ethicon asserts that it will have to explain this context to the jury, as well as David Letterman’s “Top Ten” list, if this evidence is admitted. Ethicon therefore contends that the presentation is irrelevant, unfairly prejudicial, and risks confusing the jury and wasting time during trial.

The plaintiffs argue that the presentation is probative because it demonstrates the potential benefits that Ethicon claimed the TVT-O provided and because it shows why Ethicon developed the TVT-O. I disagree. The presentation is a poor attempt at humor. It is not probative to any claims in this case. Even if it were probative, I would exclude it under Rule 403 for its risk of unfair prejudice and its potential to waste time in trial. Accordingly, Ethicon’s motion on this issue is **GRANTED**.

- Ethicon’s Motion 10: To Exclude Evidence of PA Consulting Group Report

Ethicon argues that the PA Consulting Group report titled “Investigating Mesh Erosion in Pelvic Floor Repair” should be excluded as irrelevant. It argues that the report was created to aid in producing a new mesh product for the treatment of pelvic organ prolapse, not stress urinary

incontinence. It also argues that the erosion rates used in the report are irrelevant and unfairly prejudicial because they are not specifically related to the TVT-O, but rather to many other polypropylene mesh products. I denied this same motion in *Lewis v. Johnson & Johnson*:

Ethicon's arguments are misleading. While Ethicon argues that the report was written only to address issues related to pelvic organ prolapse, the report itself states that Ethicon asked PA Consulting Group "to conduct a broad analysis of the problem of mesh erosion[.]" . . . The report does not state anywhere that it was examining erosion only as it relates to pelvic organ prolapse; rather, it discusses mesh erosion generally, in line with the broad analysis requested by Ethicon. Although the overall purpose of the report may have been to aid Ethicon in developing a next-generation device for pelvic organ prolapse, its discussion of general mesh erosion is relevant to the plaintiffs' claims. It also contains erosion rates of mesh, which have probative value.

In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig., No. 2:12-cv-4201, 2014 WL 505234, at *11 (S.D. W. Va. Feb. 5, 2014). This reasoning applies with equal force here. Accordingly, Ethicon's motion on this issue is **DENIED**.

- **Ethicon's Motion 15: To Exclude Evidence Regarding Alleged Problems with TVT-O Sheath Removal**

Ethicon moves to exclude evidence or argument that physicians have encountered problems removing the sheath from the TVT-O before implantation. According to one of the plaintiffs' experts, physicians experienced difficulty removing the sheath, which can potentially cause roping and curling of the mesh. (*See* Rosenzweig Report [Docket 282-17], at 64-67). Ethicon argues that this evidence is irrelevant, overly prejudicial, and a waste of time because no witness will testify that there was a problem with the removal of the sheath attached to Ms. Huskey's TVT-O, or that Ms. Huskey sustained any injury as a result of sheath removal. (*See* Ethicon's Mem. in Supp. of Omnibus Mot. in Limine [Docket 283], at 25-26).

Contrary to Ethicon's suggestions, this evidence is relevant. As I have already held, "the TVT-O's potential to rope and fray . . . and complications associated with small pore mesh are"

relevant to the plaintiffs' failure-to-warn claim. *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362287, at *5 (S.D. W. Va. July 8, 2014). Thus, hearing this evidence will not be a waste of time or unfairly prejudicial. Accordingly, this motion is **DENIED**.

III. Ethicon's Daubert Motion Challenging Dr. Erin Carey

Ethicon moves to limit the opinions of Dr. Erin Carey [Docket 275]. For the reasons explained below, the motion is **GRANTED**. Before I take up Ethicon's arguments, I must provide some background information on this motion. I have already resolved a dozen *Daubert* challenges in this case, and the deadline for filing *Daubert* challenges has passed. However, I permitted the plaintiffs to use Dr. Carey for the limited purpose of rebutting the supplemental expert report of Dr. Christina Pramudji. (*See* Order [Docket 224]). All rebuttal expert reports were due on March 28, 2014, but Dr. Pramudji supplemented her expert report on April 9, 2014, with new opinions. I then permitted the plaintiffs to use Dr. Carey to rebut these supplemental opinions, which they have done. Ethicon argues that several of Dr. Carey's opinions are untimely because they are not actually rebuttal opinions, but rather opinions that concur with Dr. John Steege, another expert witness for the plaintiffs.

Dr. Carey's rebuttal report states that "[t]his report offers rebuttal opinions and confirms my agreement with the opinions provided in Dr. Steege's original expert report[.]" (Carey Rebuttal Report [Docket 275-1], at 2). Dr. Carey then simply lists six opinions "originally offered by Dr. Steege" with which she agrees. (*See id.*). The report provides no explanation whatsoever for the bases of the opinions that concur with Dr. Steege's opinions. Therefore, there is no way to verify that these opinions are reliable. Further, because these opinions are not expressly in rebuttal to Dr. Pramudji's opinions, they are new opinions and they are untimely.

The plaintiffs contend that it would be premature to exclude these opinions because neither they nor the court “presently know what Dr. Pramudji’s specific testimony will entail at trial.” (Pls.’ Resp. to Defs.’ Mot. to Limit the Test. of Erin Teeter Carey, MD MSCR [Docket 298], at 3). The plaintiffs contend that these opinions may be necessary to rebut Dr. Pramudji at trial. While the plaintiffs may not know *exactly* what Dr. Pramudji will say at trial, Dr. Pramudji will not be permitted to give testimony outside the scope of her expert report. Similarly, Dr. Carey will not be permitted to testify about matters the plaintiffs *speculate* Dr. Pramudji might say. Accordingly, Dr. Carey’s six opinions that agree with Dr. Steege are **EXCLUDED** as unreliable and untimely.

Ethicon also argues that Dr. Carey’s opinion regarding interstitial cystitis is not helpful to the jury. I previously excluded Dr. Pramudji’s opinion on this topic, and Dr. Carey’s opinion merely rebuts Dr. Pramudji’s now-excluded interstitial cystitis opinion. Accordingly, Dr. Carey’s interstitial cystitis rebuttal opinion is moot and no longer helpful, and it is **EXCLUDED**.

IV. Spoliation

Ethicon has separately filed a motion in limine to exclude evidence related to spoliation [Docket 274]. The plaintiffs have repeatedly alleged that Ethicon lost or destroyed documents relevant to this multidistrict litigation. On February 4, 2014, Magistrate Judge Eifert held that Ethicon’s actions were negligent, not willful or deliberate, and denied the plaintiffs’ motions for severe sanctions, such as default judgment, striking of defenses, or offering an adverse instruction in every case. (*See In re Ethicon, Inc., Pelvic Repair System Prods. Liab. Litig.*, MDL No. 2327, Pretrial Order #100 [Docket 1069]). However, Judge Eifert recommended that I allow the plaintiffs “the opportunity to introduce evidence regarding Ethicon’s loss of relevant documents on a case-by-case basis, and, when appropriate, to tender an adverse inference instruction.” (*Id.* at 42-43). The plaintiffs have since asked Judge Eifert to reconsider Pretrial Order #100, claiming

that they have discovered new evidence that establishes that Ethicon's duty to preserve evidence began earlier than previously thought. (*See* Pls.' Request for Clarification and Reconsideration, *In re Ethicon, Inc., Pelvic Repair System Prods. Liab. Litig.*, MDL No. 2327 [Docket 1099]).

While a motion for reconsideration is pending before Judge Eifert, the parties have indicated that they do not desire a ruling on the motion at this time. If and until Judge Eifert rules on the motion to reconsider, her original ruling remains in force and effect. Moreover, the plaintiffs have offered no evidence or argument that evidence of spoliation will be relevant *in this case*. Therefore, Ethicon's motion in limine on the issue of spoliation is **GRANTED**.

V. Conclusion

For the reasons stated above, the Plaintiffs' Motions in Limine [Docket 280] are **DENIED**, the Defendants' Omnibus Motion in Limine [Docket 282] is **DENIED in part** and **GRANTED in part**, the Defendants' Motion to Limit the Testimony of Erin Teeter Carey, MD MSCR [Docket 275] is **GRANTED**, and the Defendants' Motion in Limine to Exclude Evidence of Plaintiffs' Allegations of Spoliation [Docket 274] is **GRANTED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: August 6, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE